

1 JOSEPH N. AKROTIRIANAKIS (Bar No. 197971)
2 *jakro@kslaw.com*
3 CARTER L. GEORGE (Bar No. 308775)
4 *cgeorge@kslaw.com*
5 KING & SPALDING LLP
6 633 West Fifth Street, Suite 1600
7 Los Angeles, CA 90071
8 Telephone: (213) 443-4355
9 Facsimile: (213) 443-4310

10 KATHLEEN E. MCCARTHY (*pro hac vice*)
11 *kmccarthy@kslaw.com*

12 KENNETH FOWLER (*pro hac vice*)
13 *kfowler@kslaw.com*

14 KING & SPALDING LLP
15 1185 Avenue of the Americas, 34th Floor
16 New York, NY 10036
17 Telephone: (212) 556-2100
18 Facsimile: (213) 556-2222

19 Attorneys for Defendant AMGEN INC.

20 **UNITED STATES DISTRICT COURT**
21 **CENTRAL DISTRICT OF CALIFORNIA**

22 SANDOZ INC.,

23 Case No. 2:22-cv-05326-RGK-MAR

24 Plaintiff,

25 **DEFENDANT AMGEN INC.'S NOTICE
26 OF MOTION AND MOTION FOR
27 SUMMARY JUDGMENT [FED. R. CIV.
28 P. 56]; MEMORANDUM OF POINTS
AND AUTHORITIES**

v.

Date: Monday, June 26, 2023

AMGEN INC.,

Time: 9:00 a.m.

Defendant.

Place: Courtroom 850

**Filed Concurrently: L.R. 56-1 Statement
of Uncontested Facts and Conclusions
of Law; Declaration of Joseph N.
Akrotirianakis and Exhibits; [Proposed]
Findings of Fact and Conclusions of Law;
[Proposed] Judgment**

29
30 **REDACTED VERSION OF DOCUMENT PROPOSED
31 TO BE FILED UNDER SEAL**

TO THE COURT AND PLAINTIFF AND ITS COUNSEL:

2 **PLEASE TAKE NOTICE** that, on June 26, 2023, at 9:00 a.m., or at such other
3 date and time convenient to (and ordered by) the Court, in Courtroom 850 of the Roybal
4 Federal Building and U.S. Courthouse, 255 E. Temple Street, 8th Floor, Los Angeles,
5 California, 90012, Defendant Amgen Inc. (“Amgen” or “Defendant”), will, and hereby
6 does, move this Court under Federal Rule of Civil Procedure 56 and Local Rule 56 to
7 enter judgment in favor of Amgen against Plaintiff Sandoz Inc. (“Sandoz” or
8 “Plaintiff”) with respect to each of the claims alleged in Sandoz’s complaint. This
9 motion is based on the absence of evidence to support required elements of Sandoz’s
10 claims, *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986), including the absence of
11 evidence that Amgen’s allegedly false promotional materials injured Sandoz and the
12 absence of evidence that would support any entitlement to injunctive relief.

13 This Motion is based on this Notice of Motion and the attached Memorandum of
14 Points and Authorities; the concurrently filed declaration of Joseph N. Akrotirianakis
15 and the exhibits appended thereto; any other evidence received in connection with the
16 hearing on this motion; all matters of record in the Court's files in this action; and such
17 other evidence and written or oral argument as the Court may wish to consider and
18 direct the parties to submit.

19 This Motion is made following the conference of counsel pursuant to Local Rule
20 7-3, which took place on May 16, 2023.

22 Dated: May 24, 2023

KING & SPALDING LLP

By: /s/Joseph N. Akrotirianakis
JOSEPH N. AKROTIRIANAKIS

Attorneys for Defendant AMGEN INC.

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1 **MEMORANDUM OF POINTS AND AUTHORITIES**

2 **I. INTRODUCTION**

3 More than 20 years ago, Amgen developed a landmark biologic, Neulasta®, to
4 help chemotherapy patients avoid life-threatening infections. Twelve years later,
5 Amgen improved on Neulasta® by developing the Onpro® kit, an “on-body injector”
6 that allows already very sick chemotherapy patients to receive Neulasta® without
7 having to make additional trips to a doctor’s office, medical clinic, or hospital the day
8 following chemotherapy. The innovation of Onpro® increased the number of patients
9 who receive Neulasta® at the optimal time, in accordance with the label (compliance),
10 and limits their exposure to other sick people, which in turn reduces their rates of
11 infection and keeps them on their prescribed chemotherapy regimen (dose intensity).

12 Sandoz manufactures Ziestenzo®, an FDA-approved “biosimilar” for which
13 Amgen’s Neulasta® is the “reference” biologic.¹ [REDACTED]
14 initial sales performance of Ziestenzo® following its product launch. [REDACTED]

15 [REDACTED] [REDACTED]
16 [REDACTED]
17 [REDACTED] For many months after Ziestenzo®’s
18 launch, Sandoz [REDACTED]
19 [REDACTED]. For years after
20 its launch, [REDACTED]
21 [REDACTED]. And Ziestenzo® cannot be delivered by an on-body injector, so

22 _____
23 ¹ Biologic products are unlike conventional drugs in that they “are isolated from a
24 variety of natural sources: human, animal, or microorganism.” (Dkt. 1 ¶ 17.) FDA
25 approval of a biologic is based upon submission of a biologics license application
26 (“BLA”). (Dkt. 1 ¶ 18.) Federal law permits the approval of a biologic that is
27 “biosimilar” to an FDA-approved “reference” biologic product. (Dkt. 1 ¶ 19.) FDA
28 approval of a biosimilar is based upon submission of an abbreviated BLA (“aBLA”).
(Dkt. 1 ¶ 24.) Under federal law, a biologic product has twelve years of marketing
exclusivity. 42 U.S.C. § 262(k)(7)(A).

1 it lacks the advantages of Neulasta® Onpro®—a deficiency that was particularly
2 glaring during the COVID-19 pandemic, when immunocompromised chemotherapy
3 patients could not safely travel to healthcare facilities. Instead of accepting that these
4 factors led to Ziextzenzo®’s sluggish uptake, Sandoz filed this lawsuit, [REDACTED]

5 [REDACTED] was somehow caused by Amgen promotional materials based
6 on two “real world evidence” studies, referenced in the Complaint (Dkt. 1) as the “2019
7 Amgen Study” and the “2021 Amgen Study.”

8 Fact discovery has closed, and it is clear that Sandoz has no evidence to support
9 essential elements of its claims against Amgen at a trial. To obtain any monetary relief,
10 Sandoz must prove it lost sales of Ziextzenzo® *because of* Amgen’s allegedly false
11 promotional materials. But Sandoz has no evidence that any patient, prescriber, or
12 payer *ever* used, prescribed, or paid for Neulasta® Onpro® in lieu of Ziextzenzo® as a
13 result of Amgen’s promotions. In the absence of such evidence of injury, Amgen is
14 entitled to judgment as a matter of law on Sandoz’s claims for monetary relief. Nor can
15 Sandoz establish entitlement to the injunctive relief it seeks, because promotional
16 materials based on what Sandoz alleges as the “2019 Amgen Study” have not been used
17 in commercial advertising or promotion since 2021, and Sandoz has no evidence that it
18 is likely to be harmed by promotional materials based on what Sandoz alleges as the
19 “2021 Amgen Study.” For these reasons, no trial is necessary, and the Court should
20 grant summary judgment in favor of Amgen.

21 **II. FACTUAL BACKGROUND**

22 **A. Amgen Develops Neulasta® and Neulasta® Onpro®.**

23 Chemotherapy is cytotoxic, meaning that it kills cancer cells as well as normal
24 cells, which dramatically reduces a patient’s neutrophils, a type of white blood cell that
25 helps the body fight infections. (Declaration of Joseph N. Akrotirianakis (“Akro.
26 Decl.”) Exh. B at 44, 46² [Campbell Tr. 77:7-12, 79:18-20].) Patients receiving such

28 ² References to the pages of the exhibits to the accompanying declaration of counsel

1 chemotherapy are susceptible to febrile neutropenia, a life-threatening infection. (Akro.
2 Decl. Exh. A at 20 § 14.1; Exh. B at 46 [Campbell Tr. 79:21-23].)

3 To address this problem, Amgen developed filgrastim, a biologic product
4 approved by the Food and Drug Administration (“FDA”) in 1991 and sold under the
5 brand name Neupogen®. (Akro. Decl. Exh. A at 7.) Neupogen® is a granulocyte
6 colony-stimulating factor (“G-CSF”). (Akro. Decl. Exh. A at 17 § 11.) Neupogen®
7 stimulates neutrophil production and thereby decreases the incidence of infection in
8 cancer patients undergoing chemotherapy. (Akro. Decl. Exh. A at 12 § 5.11.)

9 Innovative as it was, filgrastim requires daily injections for up to two weeks.
10 (Akro. Decl. Exh. A at 3 § 2.1.) So Amgen innovated a long-acting G-CSF known as
11 pegfilgrastim and sold under the brand name Neulasta®, which FDA approved in 2002.
12 (Akro. Decl. Exh. C at 57; Exh. D at 84 [RFA 14].) Neulasta®, like Neupogen®,
13 reduces the risk of infection in patients receiving cytotoxic chemotherapy by
14 stimulating the production of neutrophils. (Akro. Decl. Exh. C at 57, 73.) Studies show
15 Neulasta® reduces the risk of febrile neutropenia by more than 94 percent. (Akro. Decl.
16 Exh. E at 96.)

17 Neulasta® improved upon Neupogen® because it is long-acting and requires
18 only one injection at the end of each chemotherapy cycle, rather than daily injections
19 for up to two weeks. (*Compare* Akro. Decl. Exh. A at 9 § 2.1, *with* Exh. C at 59 § 2.1.)
20 At the time FDA approved Neulasta®, the sole delivery device was a pre-filled syringe
21 (“PFS”—a disposable syringe that comes pre-filled with Neulasta®. (Dkt. 1 ¶ 37.) For
22 Neulasta® to be optimally effective, it must be administered at least 24 hours *after* the
23 completion of a chemotherapy cycle. The FDA-approved label for Neulasta® thus
24 instructs that it *not* be “administer[ed] . . . between fourteen days before and 24 hours
25 after administration of cytotoxic chemotherapy.” (Akro. Decl. Exh. C at 57.)

26 _____
27 refer to the consecutive pagination of the declaration and exhibits. For ease of
28 reference, internal page and line numbers are also provided for deposition transcript
exhibits.

FDA's instruction that Neulasta® be given no less than 24 hours after chemotherapy generally requires discharged cancer patients to return to their healthcare facility the day following chemotherapy. But this can be challenging for patients for many reasons, including:

- Immunocompromised chemotherapy patients may not want to return to a healthcare facility due to the risk of viral (or other) infections.
- The chemotherapy may cause a patient to feel too weak and/or nauseous to make the trip to the clinic.
- A patient might live far away from the healthcare facility, which adds to the time spent driving, the cost of transportation, the time away from work, and the additional housing costs of staying near the clinic overnight if required. Even if a patient lives nearby, she may not have access to transportation other than taxi, rideshare, or public transit, potentially exposing the patient to even more people with communicable diseases.
- A patient might have scheduling conflicts with work or family obligations.
- Weather conditions, such as snow, ice, fog, or severe rainstorms, may prevent a patient from traveling the day following a chemotherapy cycle.

(Akro. Decl. Exh. F at 102-103.)

Problems also arise for oncologists, who must have appropriate staff available on weekends or the holidays to administer Neulasta® PFS at the right time. (Akro. Decl. Exhs. F at 103.) An oncologist would accordingly be required to plan a patient's chemotherapy regimen so that the last day of each cycle did not fall one day before the healthcare facility will be closed or when the patient has an unavoidable conflict. And even then, patients may not arrive at the right time—or at all—putting the patient at risk and making ongoing cancer treatments more difficult and less effective. These are just some of the “next day” challenges that can limit compliance (and, therefore, effectiveness) when pegfilgrastim is delivered through a pre-filled syringe.

So Amgen innovated again. It developed a means to deliver Neulasta® through

1 an “on-body injector”—Onpro®—which a health care professional applies to the
2 patient’s arm or abdomen on the last day of chemotherapy. (Akro. Decl. Exh. C at 60,
3 § 2.4.) The following day, 27 hours after the device is set, the injector automatically
4 administers the required dose of Neulasta®. (Akro. Decl. Exh. C at 60, § 2.4.) This
5 automated injection eliminates the “next day” compliance challenges created by
6 requiring a patient to return to the healthcare facility. FDA approved Amgen’s on-body
7 injector, Onpro®, in December 2014. (Akro. Decl. Exh. D at 84 [RFA 16].)

8 **B. Neulasta® Biosimilar Competition Begins.**

9 When a drug company develops a medication as effective and valuable as
10 Neulasta®, competitors often seek to follow the innovator into the market. For biologic
11 medications like Neulasta®, competition may occur through biosimilars, following the
12 expiration of the marketing exclusivity period of the reference biologic. 42 U.S.C.
13 § 262(k). Biosimilars are biologic medications FDA has determined are clinically
14 similar in safety and efficacy to an FDA-approved biologic like Neulasta®. *See id.*

15 Biosimilars for Neulasta® began entering the U.S. market almost 18 months
16 earlier than Sandoz’s Ziestenzo®. (Akro. Decl. Exh. G at 123 [Delo 30(b)(6) Tr.
17 166:17-25].) FDA did not approve Sandoz’s Ziestenzo® until November 4, 2019.
18 (Akro. Decl. Exh. D at 83-84 [RFA 13].) FDA has since approved three additional
19 biosimilars, so there are presently a total of six FDA approved biosimilars. (Akro. Decl.
20 Exh. D at 85 [RFAs 20-21].) All pegfilgrastim biosimilars are available only through a
21 pre-filled syringe. (Akro. Decl. Exh. D at 86 [RFAs 23-24].) Neulasta® Onpro®
22 remains the only commercially available on-body injector. (Akro. Decl. Exh. D at 87
23 [RFA 27].)

24 **C. Sandoz Launches Ziestenzo® Late █.**

25 Sandoz first submitted its aBLA for FDA approval of Ziestenzo® in 2015. (Dkt.
1 ¶ 46.) But FDA deemed Sandoz’s application deficient and rejected it in June 2016.
26 (Akro. Decl. Exh. D at 83 [RFAs 9-11].) Addressing FDA’s reasons for rejection took
27 Sandoz almost three years, and Sandoz resubmitted its application on February 27,
28

1 2019. (Akro. Decl. Exh. D at 83 [RFA 12].) FDA approved Ziextenzo® on November
2 4, 2019. (Akro. Decl. Exh. D at 83-84 [RFA 13].)

3 By that time, Neulasta® biosimilars offered by Mylan (Fulphila®) and Coherus
4 (Udenyca®) had both already been on the market for almost a year. (Akro. Decl. Exh.
5 D at 85 [RFA 19]; Exh. G at 123 [Delo 30(b)(6) Tr. 166:17-25].) This posed a serious
6 problem for Sandoz, [REDACTED]

7 [REDACTED]
8 [REDACTED] (Akro. Decl. Exh. H at 146 ¶13; Exh. R at 255 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]. (Akro. Decl. Exh. I at 152 [Keefe Tr. 53:4-11].) [REDACTED]
12 [REDACTED]
13 [REDACTED] (Akro. Decl. Exh. J at 159-60, 162-64 [Thole Tr. 61:8-
14 62:6, 76:20-78:18]; Exh. G at 114 [Delo 30(b)(6) Tr. 29:3-18]; Exh. K at 1.)

15 Ziextenzo®’s launch was plagued by multiple other issues. For example,
16 Ziextenzo® did not obtain a Healthcare Common Procedure Coding System “Q Code”
17 from the Centers for Medicare & Medicaid Services (“CMS”) until many months
18 following the Ziextenzo® launch. (Akro. Decl. Exh. L at 181 [RFA 60].) [REDACTED]
19 [REDACTED]
20 [REDACTED] (Akro. Decl. Exh. M at 192 [Frame Tr. 110:13-16].) [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED] (Akro. Decl. Exh. K at 174.) [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]
27 [REDACTED] (Akro. Decl. Exh. M at 204-05 [Frame Tr. 183:23-184:8].) [REDACTED]

1 [REDACTED]
2 [REDACTED] (Akro. Decl. Exh. K at 174.)
3 [REDACTED]

4 Because FDA approves biosimilars without
5 requiring manufacturers to conduct expensive clinical trials (Dkt. 1 ¶ 24), biosimilars
6 tend to be sold at a lower price than the FDA-approved biologic. [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]

10 [REDACTED] (Akro. Decl. Exh. O at 243.)
11 And then there was the COVID-19 pandemic, which disrupted life as we know
12 it, [REDACTED], a few months after Ziextenzo® entered the
13 market. (Akro. Decl. Exh. M at 206-07 [Frame Tr. 185:9-186:2].) The obvious and
14 well-publicized risks of COVID exposure in public spaces deterred patients from
15 traveling to healthcare facilities for treatment. The risk of COVID-19 infection was
16 especially high for immunocompromised chemotherapy patients. As a result, Amgen's
17 Onpro® injector device—which already provided advantages over a pre-filled syringe
18 as a delivery device—[REDACTED]
19 [REDACTED] (Akro. Decl. Exh. M at 195 [Frame Tr. 151:4-11]; Exh. J at
20 169-70 [Thole Tr. 219:20-220:25].)
21 [REDACTED]
22 [REDACTED] (Akro. Decl. Exh. M at 211 [Frame Tr. 198:5-22]; Akro
23 Exh. G at 126 [Delo 30(b)(6) Tr. 235:4-11].)
24 [REDACTED]
25 [REDACTED] (Akro. Decl. Exh.
26 _____
27 3 [REDACTED]
28 [REDACTED] (Akro. Decl. Exh. N at 227 [Delo Tr. 175:20-24].)

1 M at 195, 199-200 [Frame Tr. 151:4-7, 157:19-158:21]; Exh. P at 246-47; Exh. Q at
2 250; Exh. R at 254-55.)

3 Finally, in Sandoz's own judgment, [REDACTED]

4 [REDACTED]
5 [REDACTED]
6 [REDACTED] (Akro. Decl. Exh. S at 258.) Sandoz replaced the Ziestenzo® brand
7 team head, Alex Thole, in June 2020, and Sheila Frame, the head of Sandoz's entire
8 North American commercial organization, including biosimilar products, in November
9 2020. (Akro. Decl. Exh. N at 223, 224 [Delo Tr. 8:18-21, 9:1-3]; Exh. M at 189-90
10 [Frame Tr. 11:22-12:7].) No Sandoz sales personnel ever complained, even in internal
11 communications, that Ziestenzo®'s sales were affected by Amgen's promotional
12 material, and [REDACTED]

13 [REDACTED] (Akro. Decl.
14 Exh. M at 214 [Frame Tr. 255:2-13].)

15 So if, as Sandoz has claimed, its Ziestenzo® sales [REDACTED]

16 [REDACTED]
17 [REDACTED]
18 [REDACTED] [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED] (Akro. Decl. Exh. G at 118-19 [Delo 30(b)(6) Tr. 77:15-78:1].)

22 **D. Sandoz Ignores Its Own Internal Analysis and Sues Amgen.**

23 Ignoring its own extensive internal documents [REDACTED]

24 [REDACTED] Sandoz filed this lawsuit against Amgen,
25 asserting Amgen was the cause of lost business. Sandoz claims some of Amgen's
26 promotional materials for Neulasta® Onpro® are false or misleading. In fact, Amgen's
27 promotions accurately summarized the results of two real world studies.

28 The first promotion (the "Retrospective Study promotion") summarized a

1 retrospective study of real-world data concerning rates of febrile neutropenia in patients
2 who received Neulasta® Onpro® and patients who received Neulasta® PFS. (Akro.
3 Decl. Exh. T at 305-06.) The second promotion (the “Prospective Study promotion”)
4 summarized a prospective study that observed patients who qualified for G-CSF therapy
5 based on National Comprehensive Cancer Network guidelines. (Akro. Decl. Exh. U at
6 308-09.) The Prospective Study compared rates of febrile neutropenia in those
7 receiving Neulasta® through the Onpro® device and those treated with other febrile
8 neutropenia prophylaxis options. (Akro. Decl. Exh. U at 308-09.) The Prospective
9 Study promotion remains in use; Amgen stopped using the Retrospective Study
10 promotion in commercial advertising or promotion in 2021. (Dkt. 1 ¶ 89; Akro. Decl.
11 Exh. B at 50-51, 53 [Campbell Tr. 160:20-161:1, 279:20-23].)

12 Neither of Amgen’s promotional materials mentions Sandoz or Ziextenzo®.
13 (Akro. Decl. Exh. L at 182 [RFAs 77-78].) There is no evidence that any patient,
14 prescriber, or payer relied on Amgen’s promotions to Sandoz’s detriment: Sandoz can
15 point to no evidence that it lost any Ziextenzo® sales to Neulasta® Onpro® because of
16 Amgen’s promotions. Nor has Sandoz conducted a survey relating to the Amgen
17 promotions. Sandoz nonetheless sued Amgen for false advertising under the federal
18 Lanham Act, California False Advertising Law (“FAL”), and California Unfair
19 Competition Law (“UCL”), seeking damages, disgorgement, and injunctive relief.

20 **III. LEGAL STANDARD**

21 Under Rule 56(a), summary judgment is appropriate where “there is no genuine
22 issue as to any material fact and the movant is entitled to judgment as a matter of law.”
23 Fed. R. Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). When,
24 as here, the plaintiff bears the burden of proof on its claims, the defendant may prove
25 the “absence of a genuine issue of material fact” merely by “pointing out to the district
26 court . . . that there is an absence of evidence to support the [plaintiff’s] case.” *Celotex*,
27 477 U.S. at 325.

28

1 **IV. ARGUMENT**

2 Amgen is entitled to summary judgment because, fact discovery now having
3 closed, it is clear that Sandoz has no evidence to support an essential element of its
4 claims: Injury. Specifically, Sandoz has no evidence that it has suffered any injury
5 caused by Amgen's allegedly false promotional materials. That entitles Amgen to
6 summary judgment on Sandoz's Lanham Act claims for damages and disgorgement, its
7 UCL claim, and its FAL claim. Similarly, Amgen is entitled to summary judgment on
8 Sandoz's claims for injunctive relief because Sandoz has no evidence that it is likely to
9 be harmed by Amgen's promotional materials in the future. For these reasons, no trial
10 is required, and the Court should enter judgment in Amgen's favor.

11 **A. Summary Judgment Is Proper on Sandoz's Lanham Act Claims for
12 Damages and Disgorgement and UCL and FAL Claims Because Sandoz
13 Cannot Prove Injury Caused by Amgen's Promotional Materials.**

14 For Sandoz to succeed on its Lanham Act claims for damages and disgorgement,
15 its UCL claim, and its FAL claim, it must prove it suffered an injury caused by Amgen's
16 allegedly false promotional materials. In a "suit for damages under" the Lanham Act,
17 "actual evidence of some *injury resulting from the deception* is an essential element of
18 the plaintiff's case." *Harper House, Inc. v. Thomas Nelson, Inc.*, 889 F.2d 197, 210
19 (9th Cir. 1989) (emphasis added). The same is true when a plaintiff seeks disgorgement,
20 which is inappropriate without "proof of past injury or causation." *TrafficSchool.com,
Inc. v. Edriver Inc.*, 653 F.3d 820, 831 (9th Cir. 2011). California's FAL and UCL
21 likewise require a plaintiff to prove that its alleged "economic injury was the result of,
22 i.e., caused by, the unfair business practice or false advertising." *Kwikset Corp. v.
Super. Ct.*, 51 Cal. 4th 310, 322 (2011); *see Quidel Corp. v. Siemens Med. Solutions
USA, Inc.*, 2021 WL 4622504, at *1 n.1, 2-3 (9th Cir. Oct. 7, 2021) (affirming summary
25 judgment in favor of defendant on plaintiff's Lanham Act, FAL, and UCL claims for lack
26 of injury).

28 Sandoz cannot make the requisite showing of injury. Sandoz has no evidence

1 that any patient, physician, or insurer chose Neulasta® Onpro® over Ziestenzo® as a
2 result of Amgen's allegedly false promotional materials.⁴ Nor is Sandoz entitled to a
3 presumption of injury, since Amgen's promotions did not directly compare Neulasta®
4 Onpro® with Ziestenzo®, and the relevant market has multiple competitors in addition
5 to Amgen and Sandoz. No trial is required, and the Court should summarily adjudicate
6 Sandoz's claims for monetary relief.

7 **1. There is No Evidence Sandoz Was Injured by Amgen's
8 Promotional Material.**

9 There is no genuine dispute of material fact concerning whether Sandoz can
10 prove injury because no evidence exists from which a reasonable factfinder could
11 conclude Sandoz lost any sales as a result of Amgen's allegedly false promotional
12 materials. *See VBS Distrib., Inc. v. Nutrivila Labs., Inc.*, 811 F. App'x 1005, 1007 (9th
13 Cir. 2020) ("Summary judgment is . . . proper when the plaintiff fails to present any
14 evidence of injury resulting from defendants' deception.").⁵

15 To prove lost sales caused by Amgen, Sandoz must introduce evidence that
16 Amgen's promotional materials caused a patient, prescriber, or payer who otherwise
17 would have taken, prescribed, or reimbursed Ziestenzo® to choose Neulasta® Onpro®
18 instead. It is not enough for Sandoz to prove patients, prescribers, or payers
19

20 ⁴ The intended audience for the promotion of the results of the Retrospective Study and
21 the Prospective Study was prescribers and payers, and it is undisputed that the results
22 of either study were never promoted to patients. Sandoz alleges, however, that "[u]pon
23 information and belief, Amgen has influenced physicians to prescribe, *patients to
purchase and take*, and payers to reimburse Neulasta® Onpro® in lieu of Sandoz's
24 Ziestenzo® as a result of Amgen's false and misleading advertising." (Dkt. 1 ¶ 136
25 (emphasis added).) For ease, this motion is framed with respect to the precise injury
Sandoz alleges in the Complaint.

26 ⁵ Although a plaintiff may also prove injury through reputational harm, reputation is not
27 at issue here because Amgen's allegedly false promotions do not refer to Sandoz or
Ziestenzo® "by name" or "equat[e] [Ziestenzo®] with an inferior product." *Lexmark*,
28 572 U.S. at 138 (cleaned up). Sandoz has no evidence of reputational harm in any event.

1 misinterpreted Amgen’s materials (though, without a survey, Sandoz cannot do even
2 that). *See Quidel Corp. v. Siemens Med. Sols. USA, Inc.*, 2020 WL 4747724, at *7 (S.D.
3 Cal. Aug. 17, 2020) (holding plaintiff “confuse[d] the assertion that physicians received
4 false or misleading advertising with the assertion that those physicians then took action
5 . . . and this caused damage”), *aff’d*, 2021 WL 4622504. Nor is it enough for Sandoz to
6 prove it lost sales of Ziestenzo®—or even that it lost those sales to Neulasta® Onpro®
7 (though Sandoz cannot do that either). Instead, Sandoz must specifically prove a
8 “causal connection” between its lost sales and “the defendant’s advertising.” *Harper*
9 *House*, 889 F.2d at 210; *see Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572
10 U.S. 118, 140 (2014) (holding plaintiff must show “an injury to a commercial interest
11 in sales or business reputation proximately caused by the defendant’s
12 misrepresentations”); *Verisign v. XYZ.COM LLC*, 848 F.3d 292, 299 (4th Cir. 2017)
13 (“To recover damages under the Lanham Act, [plaintiff] must show not only false
14 advertising by [defendant], but also that [defendant’s] statements caused [plaintiff]
15 actual damages.”).⁶

16

17 ⁶ *See also Grasshopper House, LLC v. Clean & Sober Media, LLC*, 2021 WL 3702243,
18 at *2 (9th Cir. Aug. 20, 2021) (affirming summary judgment for defendant “because
19 [p]laintiff had no evidence or witnesses it could present as to any actual damages that
20 flowed from the false advertisement”); *Verisign*, 848 F.3d at 300-01 (affirming summary
21 judgment for defendant because plaintiff did not prove its lost sales were “causally
22 linked” to “false statements”); *Wall & Assocs., Inc. v. Better Business Bureau of Cent.*
23 *Va., Inc.*, 685 F. App’x 277, 279 (4th Cir. 2017) (affirming dismissal of Lanham Act
24 complaint because plaintiff did “not identify a single consumer who withheld or
25 cancelled business with it or pointed to a particular quantum of diverted sales or loss of
26 goodwill and reputation resulting directly from reliance on any false or misleading
27 representations”); *BMMG, Inc. v. Am. Telecasat Corp.*, 42 F.3d 1398 (Table), at *1 (9th
28 Cir. 1994) (affirming summary judgment for defendant because plaintiff did “not link
the loss of sales to the alleged deception”); *Telecredit Serv. Corp. v. Elec. Trans. Corp.*,
974 F.2d 1343 (Table), at *2 (9th Cir. 1992) (affirming summary judgment for
defendant because plaintiff “offered no evidence whatsoever that any retailer quit using
or failed to start using [its] services because of” false advertising); *Quidel*, 2020 WL
4747724, at *7 (granting summary judgment to defendant because plaintiff “produced
no evidence of lost profits that resulted from false advertising towards physicians”);

1 Sandoz has no evidence it lost even a single Ziestenzo® sale to Neulasta®
2 Onpro® as a result of Amgen's allegedly false promotional materials. [REDACTED]
3 [REDACTED]
4 [REDACTED]

5 [REDACTED] (Statement of Uncontested Facts ("SUF") ¶ 1.) And Sandoz has not
6 identified any document from its files—not one email, spreadsheet, presentation, or any
7 other evidence, whether or not admissible at trial—tending to prove it lost sales to
8 Amgen because of Amgen's promotions.

9 When pressed in discovery for any evidence of injury, all Sandoz has done is
10 reference Amgen documents that speak to other issues. These documents, however, do
11 not provide any evidence of injury to Sandoz (*i.e.*, that a patient, prescriber, or payer
12 chose Neulasta® Onpro® over Ziestenzo®) because of Amgen's allegedly false
13 promotions—[REDACTED]

14 [REDACTED] (Akro. Decl. Exh. N at 229-33 [Delo Tr. 207:19-211:7]; Exh. G at 129-30, 131-
15 36, 138-40 [Delo 30(b)(6) Tr. 254:4-255:3, 256:8-261:6, 266:5-268:16]; Exh. V at 322-
16 23, 327, 328 [Li 30(b)(6) Tr. 207:4-208:4, 212:9-17, 213:6-14].) [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]

21 [REDACTED] (*E.g.*, Akro. Decl. Exhs. W, X, Y.) [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED] (Akro. Decl. Exhs. Z, AA.) [REDACTED]
25 [REDACTED]

26 _____
27 *Robinson v. Best Price Distrib., LLC*, 2022 WL 4596601, at *2-3 (C.D. Cal. Aug. 12,
28 2022) (Klausner, J.) (dismissing Lanham Act counterclaim for failure to prove that
defendant lost customer's "*because of* [plaintiff's] false advertisements").

1 [REDACTED]. (Akro. Decl. Exh. AA.)
2 [REDACTED]
3 [REDACTED] [REDACTED]
4 [REDACTED]
5 [REDACTED] [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED] (Akro. Decl. Exh. P at 246-47; Exh. BB at 421.)⁷
9 [REDACTED]
10 [REDACTED]
11 [REDACTED] [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED] (Akro Decl. Exh. R at 1-2.) With three other products already on the
15 market, [REDACTED]. (Akro Decl.
16 Exh. R at 1-2.) [REDACTED]
17 [REDACTED]
18 [REDACTED] (Akro Decl. Exh. R at 1-2.) [REDACTED]
19 [REDACTED] (Akro. Decl. Exh. J
20 at 167 [Thole Tr. 205:13-18]). [REDACTED]
21 _____
22 7 [REDACTED]
23 [REDACTED] That is another reason Sandoz cannot prove injury caused by
24 Amgen's promotions. *See Grasshopper House*, 2021 WL 3702243, at *1-2 (affirming
25 summary judgment to defendant because plaintiff's damages expert could not prove
26 "causation of damages" because "he discounted competing causal factors without an
27 adequate basis"); *cf. Allergan USA Inc. v. Imprimis Pharm., Inc.*, 2019 WL 12661090,
28 at *1 (C.D. Cal. May 16, 2019) (excluding damages expert who "fail[ed] to attribute
damages to any or even all of [defendant's] false ads, or to account [for] a handful of
potential alternative factors").

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED] (Akro. Decl. Exh. M at 195, 196, 199-200 [Frame Tr. 151:4-7, 152:7-16,
6 157:19-158:21]; Akro Exh. G at 126 [Delo 30(b)(6) Tr. 235:4-11].) None of these
7 issues has anything to do with the challenged Amgen promotional materials.

8 **2. Sandoz Is Not Entitled to a Presumption of Injury.**

9 In the absence of any actual evidence of injury caused by Amgen’s allegedly false
10 promotional materials, Sandoz has sought to invoke a *presumption* of injury. But no
11 such presumption exists “[w]hen advertising does not directly compare defendant’s and
12 plaintiff’s products [or] when numerous competitors participate in a market.” *Harper*
13 *House*, 889 F.2d at 209 n.8; *accord Quidel*, 2021 WL 4622504, at *2;
14 *TrafficSchool.com*, 653 F.3d at 826. That is the case here, where Amgen’s promotions
15 do not directly compare Neulasta® Onpro® to Zixtenzo®, and the market has
16 numerous competitors in addition to Sandoz and Amgen.

17 Amgen’s promotional materials do not “directly compare” Neulasta® Onpro® to
18 Zixtenzo®. *Quidel*, 2021 WL 4622504, at *2. Amgen’s promotions do not even
19 mention Zixtenzo®—or Sandoz. (SUF ¶ 2.) Rather the Retrospective Study
20 promotion compared Neulasta® Onpro® to Neulasta® PFS, and the Prospective Study
21 promotion compared Neulasta® Onpro® to other options including the entire category
22 of products without on-body injectors, which includes Neulasta® PFS, multiple
23 biosimilars other than Zixtenzo®, and other treatment options. (Dkt. 1, Exhs. 1, 6.)
24 Courts have routinely rejected a presumption of injury for similar promotions.⁸

25 _____
26 ⁸ E.g., *Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 2011 WL 4852472, at *3
27 (C.D. Cal. Oct. 12, 2011) (rejecting presumption because advertisement referred to “a
28 generic product or class of products”); *Out of the Box Enters., LLC v. El Paseo Jewelry
Exch., Inc.*, 2012 WL 12893690, at *13 (C.D. Cal. May 11, 2012) (rejecting

Nor are Amgen and Sandoz “in a two-player market.” *Quidel*, 2020 WL 4747724, at *11. At all times relevant to this lawsuit, there have been Neulasta® and at least three (and as many as six) FDA-approved pegfilgrastim biosimilars. (SUF ¶ 3.) Courts reject a presumption of injury in these circumstances, as well. *See Harper House*, 889 F.2d at 209 n.8 (finding presumption improper “when numerous competitors participate in a market”); *Out of the Box*, 2012 WL 12893690, at *13 (rejecting presumption because plaintiff and defendant were not “the only two [competitors] in a market”); *Falcon Stainless*, 2011 WL 13130703, at *15 (rejecting presumption because defendant had five competitors).

For these reasons, Sandoz is “not entitled to a presumption of injury.” *Quidel*, 2020 WL 4747724, at *11. Sandoz must instead proffer “actual evidence” of injury. *Harper House*, 889 F.2d at 210. As discussed above, it has not done so.

3. Sandoz’s Failure to Prove Injury Precludes It from Recovering Damages or Disgorgement under the Lanham Act and Forecloses Its UCL and FAL Claims.

Because of Sandoz’s failure to prove any injury caused by Amgen’s promotional materials, Amgen is entitled to summary judgment on Sandoz’s Lanham Act claims for damages and disgorgement, its UCL claim, and its FAL claim.

First, “actual evidence of some *injury resulting from the deception* is an essential element of” a “suit for damages” under the Lanham Act. *Harper House*, 889 F.2d at 210; *accord Quidel*, 2021 WL 4622504, at *2-3; *Grasshopper House*, 2021 WL

presumption because advertisement did “not directly compare defendant’s and plaintiff’s products” (cleaned up)); *Falcon Stainless, Inc. v. Rino Cos.*, 2011 WL 13130703, at *15 (C.D. Cal. Oct. 21, 2011) (rejecting presumption because advertisement “made comparisons to five other products”), *aff’d*, 572 F. App’x 483 (9th Cir. 2014); *Munchkin, Inc. v. Playtex Prods., LLC*, 2012 WL 12886205, at *5 (C.D. Cal. Oct. 4, 2012) (rejecting presumption because advertisement “did not mention [plaintiffs] by name”), *aff’d*, 600 F. App’x 537 (9th Cir. 2015); *CKE Rest. v. Jack in the Box, Inc.*, 494 F. Supp. 2d 1139, 1146 (C.D. Cal. 2007) (rejecting presumption because advertisements “merely refer to ‘our competitor’s product’”).

1 3702243, at *2; *Verisign*, 848 F.3d at 300-01. Sandoz's failure to prove injury thus
2 dooms its claim for damages under the Lanham Act.

3 Second, Sandoz's failure to prove injury also precludes it from disgorging
4 Amgen's profits, since “[t]he Lanham Act allows an award of profits only to the extent
5 the award ‘shall constitute compensation and not a penalty.’” *TrafficSchool.com*, 653
6 F.3d at 831 (quoting 15 U.S.C. § 1117(a)). Absent “proof of past injury or causation,”
7 there is “no way to determine with any degree of certainty what award would be
8 compensatory.” *Id.* Therefore, an “award of profits with no proof of harm” is
9 “appropriate” only in limited circumstances, none of which exist here. *Id.* Such an
10 award may be “appropriate in false *comparative* advertising cases, where it’s reasonable
11 to presume that every dollar defendant makes has come directly out of plaintiff’s
12 pocket.” *Id.* (emphasis added). But this is not a “false comparative advertising case[]”
13 because Amgen’s promotions do not “directly compare” Neulasta® Onpro® and
14 Zixtenzo®. *Id.*; *Quidel*, 2021 WL 4622504, at *2. Disgorgement without proof of
15 injury may also be appropriate when the “defendant associates its product with [the]
16 plaintiff’s noncompetitive product to appropriate good will or brand value.”
17 *TrafficSchool.com*, 653 F.3d at 831. That is not what Sandoz alleges in this case, and
18 such allegations would make no sense here, where Zixtenzo® came after and is based
19 on Neulasta®. Therefore, Sandoz cannot recover disgorgement without “any proof of
20 past injury or causation.” *Id.*; *accord Nutrition Distrib. LLC v. IronMag Labs, LLC*,
21 2018 WL 6264986, at *2 (C.D. Cal. Nov. 16, 2018) (granting summary judgment to
22 defendant on disgorgement for lack of injury); *Biocell Tech. LLC v. Arthro-7*, 2013 WL
23 12063914, at *11-12 (C.D. Cal. May 22, 2013) (same).

24 Finally, Sandoz cannot proceed with its UCL and FAL claims without evidence
25 of injury. Both statutes require proof of an “economic injury” that “was the result of, i.e.,
26 *caused by*, the unfair business practice or false advertising.” *Kwikset*, 51 Cal. 4th at
27 322. Because Sandoz cannot prove any injury “caused by” Amgen’s promotional
28 materials, its UCL and FAL claims fail as a matter of law. *Id.*; *Quidel*, 2021 WL

1 4622504, at *1 n.1; *Quidel*, 2020 WL 4747724, at *4, 12; *accord Van Patten v. Vertical*
2 *Fitness Grp.*, 847 F.3d 1037, 1049 (9th Cir. 2017) (affirming summary judgment for
3 defendant on UCL and FAL claims for failure to prove injury “caused by [d]efendants’
4 conduct”).

5 **B. Summary Judgment Is Proper on Sandoz’s Claims for Injunctive
6 Relief Because Sandoz Cannot Prove a Likelihood of Future Injury
7 Caused by Amgen’s Promotional Materials.**

8 Sandoz seeks injunctive relief in addition to monetary relief, but it is not entitled
9 to an injunction because it cannot show that it faces a “likelihood of future injury.”
10 *Lexmark*, 572 U.S. at 135; *Quidel*, 2020 WL 4747724, at *11 (cleaned up). Nor can
11 Sandoz show that Amgen’s promotional materials would be the “proximate cause” of
12 any future injury. *Lexmark*, 572 U.S. at 127; *Williams & Cochrane, LLP v. Rosette*,
13 2022 WL 4544711, at *22-23 (S.D. Cal. Sept. 27, 2022); *cf. City of Oakland v. Wells*
14 *Fargo & Co.*, 14 F.4th 1030, 1042 (9th Cir. 2021) (stating “*Lexmark* uniformly applied
15 the proximate cause test without making any distinction between the damages and
16 injunctive relief claims”).

17 First, Sandoz cannot show a likelihood of future injury caused by Amgen’s
18 Retrospective Study promotion because Amgen stopped using that promotion in
19 commercial advertising or promotion in 2021. (SUF ¶ 4.) Sandoz has no evidence
20 Amgen will ever use that promotion again. Because the Retrospective Study promotion
21 is “no longer being used” and Amgen has “no demonstrated intention of using [it] in
22 the future,” it cannot support an injunction. *Nutrition Distrib. LLC v. Lecheek Nutrition,*
23 *Inc.*, 2015 WL 12659907, at *7 (C.D. Cal. June 5, 2015) (citing *Hendrickson v. eBay*,
24 *Inc.*, 165 F. Supp. 2d 1082, 1095 (C.D. Cal. 2001); *accord Allergan USA Inc. v.*
25 *Imprimis Pharm., Inc.*, 2019 WL 3029114, at *3 (C.D. Cal. July 11, 2019) (denying
26 injunction because defendant’s “false statements [had] stopped”); *McCrary v. Elations*
27 *Co.*, 2014 WL 12561600, at *6-7 (C.D. Cal. Dec. 8, 2014) (holding plaintiff lacked
28 standing to seek injunction against allegedly false advertisements the defendant “no

1 longer utilize[d]”).

2 Second, Sandoz cannot show a likelihood of future injury caused by Amgen’s
3 Prospective Study promotion because, as explained above, Sandoz has no evidence that
4 any patient, prescriber or payer has ever chosen Neulasta® Onpro® over Ziemextenzo®
5 as a result of that promotion. *See* Section IV.A.1, above. Sandoz did not even conduct
6 a survey regarding the challenged Amgen promotions. (SUF ¶ 5.) Nor does Sandoz
7 have evidence of any other injury the Prospective Study promotion might cause. [REDACTED]

8 [REDACTED]
9 (Akro. Decl. Exh. G at 118-19 [Delo 30(b)(6) Tr. 77:15-78:1].) Sandoz thus cannot
10 prove it is likely to be harmed by the Prospective Study promotion in the future. *See*
11 *Williams & Cochrane*, 2022 WL 4544711, at *22-23 (granting summary judgment on
12 claim for injunctive relief because plaintiff could not “establish causation” or
13 “likelihood of future injury”); *Quidel*, 2020 WL 4747724, at *11 (same, because
14 plaintiff had no evidence of “monetary loss” and had “not argued that there is any loss
15 beyond this”).

16 **V. CONCLUSION**

17 For the foregoing reasons, the Court should grant Amgen’s motion and enter
18 judgment in Amgen’s favor on all of Sandoz’s claims.

19
20 Dated: May 24, 2023

KING & SPALDING LLP

21
22 By: /s/Joseph N. Akrotirianakis
23 JOSEPH N. AKROTIRIANAKIS

24 Attorneys for Defendant AMGEN INC.
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1 **LOCAL RULE 11-6.2 CERTIFICATE OF COMPLIANCE**
2

3 The undersigned, counsel of record for Amgen Inc., certifies that this brief
4 contains 6,401 words, which complies with the word limit of L.R. 11-6.1.

5
6 Dated: May 24, 2023

KING & SPALDING LLP

7
8 By: /s/Joseph N. Akrotirianakis
9 JOSEPH N. AKROTIRIANAKIS

10 Attorneys for Defendant AMGEN INC.
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